

WASHINGTON LEGAL FOUNDATION

2009 MASSACHUSETTS AVENUE, N.W.

WASHINGTON, D. C. 20036

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Dockets Management Branch
U.S. Department of Health and Human Services
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: WLF Opposition to the Center for Science in the Public Interest's Citizen
Petition To Require Health Messages on Soft Drinks, Docket No. 2005P-0282

Dear Dockets Management Branch Clerk:

The Washington Legal Foundation (WLF) hereby submits this opposition to the Citizen Petition of the Center for Science in the Public Interest (CSPI), *Petition To Require Health Messages on Soft Drinks Containing High-fructose Corn Syrup and other Caloric Sweeteners*, pending before the Food and Drug Administration (FDA). As more fully described herein, WLF requests that the FDA deny the petition because the warning labels on soft drinks suggested by CSPI are neither required by law nor warranted as a matter of sound public policy.

Current labeling requirements and practices, as well as common sense, sufficiently enable consumers to make well-informed decisions regarding soft drink consumption. The CSPI petition, which claims that the excessive consumption of full-calorie sodas by adolescents and high-school students is the cause of childhood obesity and related illnesses, lacks a sound factual and scientific basis. There are a number of causes of obesity, including one's lifestyle, physical activity, and family history. In any event, studies show that soft drink consumption overall has declined in recent years, and that purchases of full-calorie soft

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drinks during school hours averaged no more than *one* 12 ounce can per *week* for a typical high school student. If the petition were granted, then warning labels would be required for other beverages, such as 100 percent fruit juices, many of which have *more* calories and *more* sugar, ounce for ounce, than do soft drinks. For these and other reasons, the CSPI petition should be denied.

I. Interests of WLF

WLF is a national, nonprofit public interest law and policy center based in Washington, D.C., that opposes unnecessary, costly, and burdensome government regulations. WLF devotes substantial resources to FDA-related issues at the agency level and in the courts challenging excessive regulatory and enforcement practices that are harmful to public health and violate First Amendment protections.

For example, WLF successfully challenged the constitutionality of certain FDA restrictions on the dissemination of so-called "off label" truthful speech about FDA-approved products. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed* (D.C. Cir. 2000). WLF also opposes unnecessary labeling requirements, and supports the First Amendment rights of companies to advertise and provide consumers with information about their products. For example, WLF recently filed comments with the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of Treasury to allow beverage manufactures to voluntarily provide caloric, serving size, and alcohol content on beer, wine, and distilled spirits. Such ingredient disclosures are currently prohibited. *See, e.g., Advanced Notice of Proposed Rulemaking; Labeling and Advertising of Wines, Distilled*

Spirits and Malt Beverages (Sept. 26, 2005). In addition, WLF has submitted comments with the TTB and its predecessor agency, the Bureau of Alcohol, Tobacco & Firearms (BATF), in a number of other regulatory proceedings that deal with labeling and related issues. *See, e.g., Proposed Rule on Flavored Malt Beverages and Related Proposals* (Oct. 21, 2003); *Advanced Notice of Proposed Rulemaking Regarding Alcohol Beverage Warning Statement* (Aug. 17, 2001); *Notice of Proposed Rulemaking Regarding Health Claims in the Labeling and Advertising of Alcohol Beverages* (Feb. 18, 2000). WLF's Legal Studies Division also publishes policy papers on related subjects. *See, e.g., Ann Grimaldi, Would You Like A Prop 65 Warning With Those Fries?* (WLF Legal Backgrounder, Nov. 18, 2005).

II. CSPI Petition Should Be Rejected

On July 13, 2005, CSPI submitted a 37-page petition requesting that the FDA require certain rotating warning labels on soda cans and bottles. The warning labels suggested by CSPI include: "Drinking too much (non-diet) soft drinks may contribute to weight gain;" "For better health, the U.S. Government recommends that you limit your consumption of (non-diet) soft drinks;" and "To help protect your waistline and your teeth, consider switching to [sic] soft drinks."¹ CSPI Pet. at 3.

CSPI claims that these warning labels are needed to inform consumers about the risk of becoming overweight or obese allegedly associated with the excessive consumption of full-

¹ This last warning appears to be a typographical error; CSPI probably intended that the warning suggest that consumers switch to "*diet* soft drinks." Another proposed CSPI warning label would require disclosure of the milligrams of caffeine in soda and the statement that caffeine is a "mildly addictive stimulant drug. Not appropriate for children."

calorie soft drinks. However, consumers are well aware of the caloric and sugar content of soft drinks as clearly provided by current nutritional labeling requirements. Furthermore, CSPI has not shown that there is a direct causal link between obesity and the consumption of full-calorie soft drinks. In any event, such soft drink consumption has been decreasing over the years.

A. The Causal Link Between Obesity and Soda Consumption Is Lacking

As a general matter, many consumers enjoy drinking or eating sweetened foods, and in moderation, such foods are not harmful. According to the American Dietetic Association (ADA), "people are born liking the sensation of sweetness" and that "sweet foods and beverages offer a pleasurable addition to a meal or snack."² The ADA suggested that dieticians can help consumers in addressing health and other issues surrounding obesity by "recogniz[ing] that sweeteners can add to the pleasure of eating . . . [and] facilitate the incorporation of sweeteners within the context of the *total* diet instead of simply examining the health benefits or risks of *individual* foods or beverages."³ In addition, "consumers can safely enjoy a range of nutritive and nonnutritive sweeteners when consumed in a diet that is guided by current federal nutrition recommendations."⁴ In a 2002 report, the ADA reiterated what anyone with common sense already knows, namely, that "[i]f consumed in moderation

² American Dietetic Association, *Use of Nutritive and Non-Nutritive Sweeteners*, http://www.eatright.org/Member/PolicyInitiatives/index_21018.cfm.

³ *Id.*

⁴ *Id.*

with appropriate portion size and combined with regular physical activity, *all* foods can fit into a healthful diet."⁵

The CSPI petition is based on the questionable premise that the problems of overweight and obesity in America are due in large measure to the consumption of full-calorie sodas. While there is no denying that Americans are getting fatter, it is beyond peradventure that a person's weight is due to a multiplicity of factors, including his or her physical activity or exercise regimen, lifestyle (whether sedentary or active), and family or genetic history. Indeed, a recent study shows that there is no causal link between snack food and soda consumption and obesity.⁶ As its authors note, the "inclusion of sugar-sweetened beverages in the snack food category did not meaningfully change the results. Regardless of the definition of snack foods, there was not a strong association between intake of snack foods and weight gain."⁷ Moreover, the overweight and obese children in the study were not eating more snack foods than the thin children.⁸ In short, snack foods, including soda, were not an important independent determinant of weight gain among children and adolescents.

⁵ American Dietetic Association, *Total Diet Approach to Communicating Food and Nutrition Information*, http://www.eatright.org/Public/Other/index_adar_0102.cfm (emphasis added).

⁶ John Luik, *Kicking the Can* (July 8, 2005), <http://www.techcentralstation.com/070805C.html> citing A.E. Field, S.B. Austin, M.W. Gillman, B. Rosner, H.R. Rockett & G.A. Colditz, *Snack Food Intake Does Not Predict Weight Change Among Children and Adolescents*, *International Journal of Obesity* (2004) 28, 1210-1216, *abstract at* <http://www.nature.com/ijo/journal/v28/n10/abs/0802762a.html>.

⁷ *Id.*

⁸ *Id.*

Because the CSPI has not even demonstrated the accuracy of the petition's stated premise, the FDA should not require additional labeling of soft drinks.

B. The Causal Link Between Dental Cavities and Soda Consumption Is Lacking

One of the rotating warning labels proposed by CSPI would state that avoiding sweetened sodas would protect children and young adults from getting cavities. CSPI Pet. at 3. But the basis for that warning presupposes that cavities are caused by drinking full-calorie soft drinks. The evidence suggests otherwise. As with the cause of obesity, there are many factors that contribute to cavities. For example, solid sticky foods containing sugar, such as granola bars or cookies, tend to cling to teeth and are likely to be a cause of cavities rather than a liquid soft drink. In addition, researchers at University of Michigan⁹ and Virginia Tech¹⁰ have found no correlation between consumption of sodas and cavities for people under the age of 25.

Accordingly, there is no sound factual basis to require warning labels on regular soft drinks regarding the risk of getting cavities from consuming such drinks in moderation. Otherwise, thousands of sugared snack foods would be subject to those same warning labels.

C. Full-Calorie Soda Consumption Is Decreasing

Recent studies indicate that soft drink consumption and purchases in the United States

⁹ Heller, K.A., Burt, B.A., Eklund, S.A., "Sugared Soda Consumption and Dental Caries in the United States," *Journal of Dental Research* 80(10) at 1949-53 (2001).

¹⁰ Forshee, R.A., Storey, M.L., "The Association of Demographics and Beverage Consumption with Dental Caries," presented to the American College of Nutrition, 42d Annual Meeting, Oct. 3-7, 2001, Orlando, Florida.

have declined over recent years. According to the *Beverage Digest 2005 Fact Book*, the average American consumed 18 (12-ounce) cans *less* in 2004 than they did in 1998. More importantly, the calorie consumption per beverage dropped 16 percent as consumers consumed more bottled water and diet soft drinks and less full-calorie sodas. *Id.*

The notion that high school students are guzzling vast quantities of soda from soft drink vending machines in the schools is also belied by the facts. A recent study commissioned by the American Beverage Association concluded that the typical teenager in high school purchased on average, at most, only *one* can of soda *per week*.¹¹ In addition, purchases of full sugared sodas to schools dropped almost 25 percent from 2002 to 2005, while sales increased approximately 20 percent for diet sodas, 22 percent for bottled water, 69 percent for sports drinks, and 15 percent for 100 percent fruit juices.¹²

D. Current Labeling on Soda Cans and Bottles Is Sufficient

Even if CSPI could demonstrate a positive association between soda consumption and obesity, consumers already have the information they need to make dietary choices. Current labeling information requires that nutritional information be disclosed, including calories and sugar content. For example, the product label of a typical 12 ounce can of a popular full-calorie cola soda discloses that it contains 140 calories and a sugar content of 39 grams. Sodas labels also disclose whether they contain caffeine, and if they do not contain caffeine,

¹¹ Robert F. Westcott, Ph.D, "Measuring the Purchases of Soft Drinks by Students in U.S. Schools," (Nov. 28, 2005).

¹² *Id.*

many prominently note that they are "CAFFEINE FREE" products.

If warning labels were to be placed on soft drinks because of the alleged role these beverages play in obesity, warning labels would have to be placed on all foods that could contribute in any way to weight gain or obesity, meaning almost all foods. As noted, a typical 12 ounce cola drink contains approximately 140 calories and 39 grams of sugar. Yet a comparable serving of 100 percent apple juice contains 180 calories and 44 grams of sugar. A 12 ounce glass of orange juice contains approximately 165 calories and 33 grams of sugar. In short, 100 percent fruit juices, such as apple juice and orange juice, often have *more* calories, ounce for ounce, and about the same or more grams of sugar. If the FDA were to require warning labels on sodas, then many so-called "healthy" beverages and foods would also be required to have them. The fact is that most any non-dietetic food eaten to excess will cause weight gain. And as reported in the FDA's Consumer Magazine, "weight loss is complex and can't be attributed to any one food product."¹³

E. CSPI's Argument That Warning Labels Are Required By Law Lacks Merit

CSPI argues that warning labels on sodas should be legally required just as warning labels are required for foods containing additives, such as aspartame or olestra. which, although deemed safe by the FDA, may cause some adverse health effects. CSPI Pet. at 33-35. However, products containing the artificial sweetener aspartame are required to have a warning because a very small percentage of people, about 1 in 15,000, are born with the

¹³ John Henkel, *Sugar Substitutes: Americans Opt for Sweetness and Lite*, FDA CONSUMER (November-December 1999).

disease phenylketonuria, "a rare inherited disease that prevents the essential amino acid phenylalanine from being properly metabolized."¹⁴ People with this disease are placed on a special diet with a severe restriction of phenylalanine from birth to adolescence or after and must consider aspartame as an additional source of phenylalanine.¹⁵ Therefore, the labels on aspartame-containing foods must state "PHENYLKETONURICS; CONTAINS PHENYLALANINE." 21 C.F.R. § 172.804(d).

The obvious distinction between beverages containing aspartame and other sweeteners such as high-fructose corn syrup (HFCS) is that full-calorie soft drinks, when consumed in moderation, are not considered dangerous to human health, whether in the short or long term. The CSPI has simply not demonstrated that HFCS sweeteners are food additives that should no longer be "generally regarded as safe" (GRAS) under Section 409(a)(2) of the Federal Food Drug and Cosmetic Act, or should otherwise require special warnings.

CSPI's further reliance on the FDA regulation that once required warning labels on food products containing the food additive olestra is easily distinguishable, and actually supports WLF's argument that no warning labels are required for sodas. In the case of products containing olestra, labeling was required to make the consumer aware that the product may cause abdominal cramping and loose stools, and may inhibit the absorption of certain vitamins and nutrients.¹⁶ These were the immediate and short term affects of

¹⁴ http://www.aspartame.org/aspartame_myths_phenyl.html

¹⁵ *Id.*

¹⁶ *Id.* at 35.

consuming olestra. However, no such immediate or short-term health problems are associated with consuming full-calorie soft drinks. Indeed, as CSPI acknowledged in its petition, the warning label required for olestra products was revoked by the FDA in 2003 “in part because the FDA determined that evidence gathered in consumer surveys after 1996 showed that there was ‘a high degree of awareness among the public’ about the possible effects of olestra.”¹⁷ Labeling was deemed to be unnecessary for products containing olestra because consumers knew what the possible health risks were. So too here, the public is generally aware that consuming excessive amounts of full-calorie sodas (or any non-diet food) over a long period of time could also affect their weight. Consumers readily have caloric and sugar content information on soda cans and bottles upon which to base their dietary decisions. In short, CSPI’s warning labels for sodas are neither necessary nor required by law.

III. Conclusion

For the foregoing reasons, WLF urges the FDA to reject CSPI’s petition requiring warning labels on soft drinks.

Respectfully submitted



Daniel J. Popeo
Chairman and General Counsel



Paul D. Karnenar
Senior Executive Counsel

¹⁷ CSPI Pet. at 35, n.151, citing 68 Fed. Reg. 46387 (Aug. 5, 2003).